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10/551,789	07/05/2006	Michael Thomas Clandinin	D4858-00059	3396

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,789	CLANDININ, MICHAEL THOMAS	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 15, 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6,7,11,13,17,21-23,25 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,7,11,13,17,21-23,25 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 15, 2009 has been entered.

Detailed Action

This office action is a response to applicant's communication submitted July 15, 2009 wherein claims 3, 13, 17, 25, 28, and 29 are amended and claims 2, 4, 5, 19, and 20 are cancelled. This application is a national stage application of PCT/CA04/00375, filed March 12, 2004, which claims benefit of US application 10/404095, now US patent 6998392, filed April 2, 2003.

Claims 3, 6, 7, 11, 13, 17, 21-23, 25, and 28-32 are pending in this application.

Claims 3, 6, 7, 11, 13, 17, 21-23, 25, and 28-32 as amended are examined on the merits herein.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 25, 28, 31, and 32 under 35 USC 103(a) for being obvious over Della Valle et al. in view if Merck in view of Schroten, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that

the administered gangliosides be at least 50% GD_3. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 17, 23, and 25 under 35 USC 102(b) for being anticipated by Williams et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the administered gangliosides be at least 50% GD_3. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 17, 19, 23, and 25 under 35 USC 102(e) for being anticipated by Berger et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the gangliosides be administered in a specific amount of up to 1g per day. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 17, 23, and 25 under 35 USC 102(b) for being anticipated by Schroten et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the subject be an adult. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 19-22 under 35 USC 103(a) for being obvious over Williams et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the administered gangliosides be at least 50% GD_3. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 15, 2009, with respect to the rejection of instant claims 17, 23, and 25 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 9-17 of US application 11/622858, has been fully considered and found to be persuasive to remove the rejection as the instant claims have been amended to require that the ganglioside be at least 50% GD_3. Therefore the rejection is withdrawn.

Information Disclosure Statement

The listing of references in the specification (pp. 7-13) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6, 7, 11, 13, 17, 21-23, 25, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ettinger (US patent 4762822, of record in previous action) in view of Pan et al. (Reference of record in previous action) in view of the Merck Manual of Diagnosis and Therapy. (Reference of record in previous action, herein referred to as Merck)

Ettinger discloses an improved food for young mammals comprising a sialic acid or a ganglioside, for example gangliosides extracted from mammalian brain, human milk, or human colostrum. (column 3 lines 5-17) This composition reduces the number of gastrointestinal disease producing microorganisms in the mammal's gastrointestinal tract. (column 1 lines 19-32) Administering the ganglioside to as subject is reasonably considered to be a method of mediating inflammation in the subject. A young mammal according to the invention refers to mammals such as humans that have not been weaned, i.e. infants. (column 4 lines 64-68) The amount of sialic acid or ganglioside is sufficient to provide about 0.0003-0.02%, preferably 0.005-0.015% of the subject's body weight. (column 6 lines 56-63) This amount would be equivalent to 9.6-640 mg for a 3.2 kg infant or 210-14000 mg for a 70 kg adult. Compositions of gangliosides were disclosed to have a lethal effect on *E.* coli in culture. (column 9 line 52 - column 10 line

28) Ettinger does not specifically disclose the various gangliosides used in the instant claims, for example GDE, GM2, GM3, and GD1b. Ettinger also does not disclose the exact amount of ganglioside (10-50 mg) administered to an infant subject or the amount of 100-1000 mg administered to an adult subject.

Pan et al. discloses a study of the ganglioside composition of human colostrum and milk, as well as cow's milk. (p. 26 paragraphs 1-3) Human colostrum contains over 50% of ganglioside GD_3, as well as a smaller amount of ganglioside GM_3. (p. 29 table 1)

Merck discloses that a typical newborn infant weighs about 3.2 kg. (p. 2084 left column fifth paragraph) Merck also discloses that certain strains of *e. coli* produce shigella toxin and can cause gastrointestinal disease. (p. 285 right column paragraphs 2-3)

It would have been obvious to one of ordinary skill in the art to administer 100-1000 mg of ganglioside to an adult or 10-50 mg to an infant or adult suffering from *E. coli* gastrointestinal infection. One of ordinary skill in the art would have been motivated to use these amounts because they fall within the broad ranges disclosed by Ettinger. When the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Furthermore it would have been obvious to administer the compositions of Ettinger to an adult mammal suffering from *E. coli* infection. One of ordinary skill in the art would have been motivated to do so because adults as well as infants can contract

this infection. One of ordinary skill in the art would reasonably have expected success because Ettinger already discloses that gangliosides are toxic to *E. coli*.

Finally it would have been obvious to use a composition comprising the specific amounts of gangliosides GM_3 and GD_3 recited in the instant claims. One of ordinary skill in the art would have been motivated to include GM_3 and GD_3 in the composition in the recited amounts because both of these gangliosides are present in significant amount in human colostrum and milk as described by Pan et al. In particular, one of ordinary skill in the art would have recognized ganglioside GD_3 as being the major ganglioside component of human colostrum. One of ordinary skill in the art would have been able to modify and select the optimal ranges for these components in order to practice the invention. Doing so is part of the ordinary and routine level of skill in the art and would therefore be reasonably expected to succeed.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted July 15, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Ettinger et al. dose not disclose a method or composition wherein at least 50% of the ganglioside is GD_3. However, Ettinger et al. does disclose a composition comprising human colostrum gangliosides, which hare disclosed by Pan et al. to comprise at least 50% of GD_3. With regard to the Pan et al. reference, Applicant argues that Pan et al. does not disclose the use to which the disclosed ganglioside formulations can be directed. However, this element is supplied by Ettinger, along with the suggestion to use human colostrum

gangliosides. The only missing link is the teaching that human colostrum contains over 50% of GD_3. One of ordinary skill in the art would merely have looked to the disclosure of Pan et al. to disclose the identity of these colostrum gangliosides, and would thereby have been motivated to use gangliosides having this specific profile with over 50% of GD_3.

Applicant also argues that Ettinger et al. does not disclose methods of treating the specific types of inflammation recited in the claims, namely inflammatory bowel disorders, disorders arising from allergic responses, diseases involving epithelial surface responses, or inflammation of the intestine, retina, or neuronal tissue. However, p. 17 paragraph 00243 of the specification as originally filed specifically discloses that enteric infections are examples of such inflammatory conditions. (i.e. inflammatory bowel disorders, disorders arising from allergic responses, diseases involving epithelial surface responses, or inflammation of the intestine, retina, or neuronal tissue) Therefore the *E. coli* infection described in the prior art is reasonably considered to fall within the limits of the claims as interpreted by the specification.

Therefore the rejection is deemed proper and maintained.

Claims 17, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US pre-grant publication 2005/0107311, of record in previous action)

Berger et al. discloses gangliosides obtained from buffalo milk which mediate anti-inflammatory effects. (p. 1 paragraphs 0018-0019) Gangliosides present include

GM3 and GD3. (p. 3 paragraph 0066) One specific type of buffalo milk (Pakistan buffalo mature milk) is analyzed and shown to have predominantly (over 50%) ganglioside GD3. (figure 1 in the drawings, also p. 2 paragraph 0031) This composition is a nutritionally complete consumable product, and therefore is a supplemented food. (p. 2 paragraph 0050) It can also be used in infant formulas. (p. 2 paragraph 0028) Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. With regard to the new limitation "an adult subject," p. 4 paragraphs 0082-0083 of Berger et al. discloses treatment of age related diseases, including Parkinson's and Alzheimer's disease. These are diseases that occur in adults, so Berger et al. therefore discloses administering the buffalo milk composition to adults. Berger et al. does not disclose a method wherein the composition comprises the specific amounts of GD3 and GM3 recited in instant claims 4-7 and 19-22. Berger et al. also does not specifically disclose a method wherein the amount of ganglioside is up to (less than) 1g per day.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Berger et al. using the specific amounts of GM_3 and GD_3 found in 21-22. One of ordinary skill in the art would have been motivated to optimize the amounts of these critical ingredients in the therapeutic composition in order to determine the optimal amounts to use to get the desired therapeutic effect. One of ordinary skill in the art would have reasonably expected success because routine optimization of the amounts of ingredients in a prior art composition is well within the ordinary and routine level of skill in the art.

Regarding the amount of ganglioside administered, one of ordinary skill in the art would have been able to optimize the dose of ganglioside to arrive at an amount within Applicant's broad claimed range. It is noted that 1g of ganglioside is approximately the amount present in about 25L of human milk, (see table 2 on p. 10 of Berger et al.) much more than a human is capable of consuming in a day. Therefore any composition intended to emulate human milk will have a ganglioside content below Applicant's upper limit.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted July 15, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Berger et al. does not disclose a composition wherein the gangliosides comprise at least 50% GD_3. However, figure 1 of the drawings in Berger et al. discloses a graph of the ganglioside profile of Pakistan buffalo milk, which clearly shows GD_3 as the predominant (over 50%)

ganglioside present in the milk. Therefore a composition comprising buffalo milk contains at least 50% GD_3. Applicant further argues that the reference does not disclose a method of reducing cholesterol. However as discussed previously, administering the composition to a subject is seen to inherently lower cholesterol, as it comprises administering the same composition to the same subject as the instant claims.

Regarding the new limitation that the dosage be "up to 1g of ganglioside per day," as discussed above, this limitation is extremely broad and would encompass any nutritional formulation having a ganglioside content even remotely resembling that of human milk. (2.1-4.3 mg/L according to p. 10 table 2 of Berger et al.) Therefore since Berger et al. is directed toward compositions having a ganglioside profile similar to that of human milk, one of ordinary skill in the art would have considered the optimal amount to be significantly less than 1g of gangliosides per day.

Therefore the rejection is deemed proper and maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 21-23, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6998392. (Cited in previous action, herein referred to as '392) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 of '392 render the claimed invention obvious. Specifically, claim 1 of '392 is drawn to a method comprising administering a ganglioside to a subject. Administering a ganglioside inherently will mediate inflammation and lower serum cholesterol. Claim 2 indicates that the ganglioside contains GD3 and/or GM3, and clam 5 recites a composition falling within the amounts of GD3 and GM3 recited in instant claims 19, 21, and 22. Claims 3 and 4 require that the composition be a supplemented liquid or food, including an infant formula, as recited in instant claims 11, 12, 23, and 24. Claim 5 discloses a specific composition of gangliosides containing over 50% GD_3. Although the claims of '392 do not specifically claim a method wherein the subject is an adult or the amount of ganglioside GD_3 is less than 1g per day, one of ordinary skill in the art would have easily determined that "a subject" includes an adult subject because adult subjects can suffer from parasitic infections. Furthermore with regard to the limitation of less than 1g of ganglioside per day, this limitation is so broad that one of

ordinary skill in the art would have easily and routinely arrived at an amount of less than 1g per day when formulating the compositions described in claims 1-5 of '392 for actual therapeutic use.

Response to Argument: Applicant's arguments, submitted July 15, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant makes no specific traversal of this argument, instead making a generic statement that "In view of the amendments to Claim 25, applicants kindly request reconsideration and withdrawal of the double patenting and provisional double patenting rejections because the present claims contain limitations not found in claims 1-5 of U.S. Patent No. 6,998,392." as this traversal makes no specific arguments as to why the rejection is incorrect, the rejection is maintained.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
9/10/2009